IC 16-42-3

Chapter 3. Uniform Food, Drug, and Cosmetic Act: Adulteration and Misbranding of Drugs or Devices

IC 16-42-3-1

Antibiotic drug defined

Sec. 1. As used in this chapter, "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance that is produced by microorganisms and that has the capacity to inhibit or destroy microorganisms in dilute solution, including the chemically synthesized equivalent of the substance.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-2

Established name defined

Sec. 2. As used in this chapter, "established name", with respect to a drug or ingredient of a drug, means:

(1) the applicable official name designated under Section 508 of the Federal Act;

(2) if there is no official name and the drug or the ingredient is an article recognized in an official compendium, the official title of the drug or ingredient in the compendium; or

(3) if neither subdivision (1) nor (2) applies, the common or usual name, if any, of the drug or the ingredient.

However, when subdivision (2) applies to an article recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia applies unless the article is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia applies.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-2.5

Duties of state veterinarian and state board of animal health

Sec. 2.5. (a) The state veterinarian shall act in place of the state health commissioner under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-2.1-23 or IC 15-2.1-24.

(b) The Indiana state board of animal health shall act in place of the state department of health under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-2.1-23 or IC 15-2.1-24.

As added by P.L.137-1996, SEC.70.

IC 16-42-3-3

Adulterated drug or device

Sec. 3. A drug or device is considered to be adulterated under the following conditions:

(1) If the drug or device consists in whole or in part of any filthy, putrid, or decomposed substance.

(2) If the drug or device has been produced, prepared, packed, or held under unsanitary conditions under which the drug or device may have been contaminated with filth or made injurious to health.

(3) If the methods used in or the facilities or controls used for a drug's manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that:

(A) the drug meets the requirements of this article as to safety; and

(B) the drug:

(i) has the identity and strength; and

(ii) meets the quality and purity characteristics;

that the drug purports or is represented to possess.

(4) If a drug's container is composed in whole or in part of any poisonous or deleterious substance that may make the contents injurious to health.

(5) If:

(A) a drug bears or contains, for purposes of coloring only, a color additive that is unsafe within the meaning of IC 16-42-2-5; or

(B) a color additive, the intended use of which in or on drugs is for purposes of coloring only, is unsafe under IC 16-42-2-5.

(6) If:

(A) the drug or device purports to be or is represented as a drug, the name of which is recognized in an official compendium; and

(B) the strength of the drug differs from or the drug's quality or purity falls below the standard set forth in that compendium;

the determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium or, in the absence or inadequacy of such tests or methods of assay, those tests or methods prescribed by the federal security administrator in regulations promulgated under the Federal Act. A drug defined in an official compendium is not considered to be adulterated under this subdivision because the drug differs from the standard of strength, quality, or purity set forth in the compendium if the drug's difference in strength, quality, or purity from the standard is plainly stated on the drug's label. If a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, the drug is subject to the requirements of the United States Pharmacopoeia unless the drug is labeled and offered for sale as a homeopathic drug. In the latter case, the drug is subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(7) If:

(A) the drug or device is not subject to the provisions of subdivision (6); and

(B) the drug's or device's strength differs from or the drug's or device's purity or quality falls below that which the drug or device purports or is represented to possess.

(8) If the drug or device is a drug and any substance has been:

(A) mixed or packed with the drug or device so as to reduce the drug's or device's quality or strength; or

(B) substituted wholly or in part for the drug.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-4

Misbranded drug or device

Sec. 4. A drug or device is considered to be misbranded under any of the following conditions:

(1) If the labeling of the drug or device is false or misleading in any way.

(2) If the drug or device is in package form unless the drug or device bears a label containing:

(A) the name and place of business of the manufacturer, packer, or distributor; and

(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

However, under clause (B) reasonable variations shall be permitted and exemptions as to small packages shall be established by rules adopted by the state department.

(3) If any word, statement, or other information required to appear on the label or labeling, under this chapter or a rule adopted under IC 16-42-1-2 is not prominently placed on the drug or device with conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms that make the label likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(4) If the drug or device:

(A) is for use by humans; and

(B) contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, methamphetamine, or sulphonmethane, or any chemical derivative of such substance, which derivative after investigation has been found to be and is designated as habit forming, by rules adopted by the state department under IC 16-42-1 through IC 16-42-4 or by regulations issued under 21 U.S.C. 352(d);

unless the label on the drug or device bears the name and quantity or proportion of that substance or derivative and the statement "Warning – May Be Habit Forming".

(5) If a drug, unless the following conditions are met:

(A) The label on the drug bears, to the exclusion of any other nonproprietary name except the applicable systematic chemical name or the chemical formula, the following:

(i) The established name of the drug, if any.

(ii) If the drug is fabricated from at least two (2) ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol and, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of those substances contained in the drug. However, the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subdivision, applies only to prescription drugs.

(B) If a prescription drug, the established name of the drug or ingredient on the label (and on any labeling on which a name for the drug or ingredient is used) is printed prominently and in type at least half as large as that used for any proprietary name or designation for the drug or ingredient.

However, to the extent that compliance with the requirements of clause (A)(ii) or clause (B) is impracticable, exemptions shall be allowed under rules adopted by the state department or by regulations promulgated under the Federal Act.

(6) Unless the drug's or device's labeling bears:

(A) adequate directions for use; and

(B) adequate warnings against use in those pathological conditions or by children where the drug's or device's use may be dangerous to health or against unsafe dosage or methods or duration of administration or application in the manner and form that is necessary for the protection of users.

However, if any requirement of clause (A) as applied to any drug or device is not necessary for the protection of the public health, the state department shall adopt rules exempting the drug or device from that requirement.

(7) If a drug purports to be a drug the name of which is recognized in an official compendium, unless the drug is packaged and labeled as prescribed in the compendium. However, the method of packing may be modified with the consent of the state department in accordance with regulations promulgated by the federal security administrator under the Federal Act. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, the drug is subject to the requirements of the United States Pharmacopoeia with respect to packaging and

labeling unless the drug is labeled and offered for sale as a homeopathic drug. In that case the drug is subject to the Homeopathic Pharmacopoeia of the United States and not to the United States Pharmacopoeia.

(8) If a drug or device has been found by the federal security administrator or the state department to be a drug liable to deterioration, unless the drug or device is packaged in a form and manner and the drug's or device's label bears a statement of such precautions as the federal security administrator or the state department requires by rule or regulation as necessary for the protection of the public health. A rule or regulation may not be established for any drug recognized in an official compendium until the federal security administrator or the state department informs the appropriate body charged with the revision of the compendium of the need for the packaging or labeling requirements and that body fails within a reasonable time to prescribe requirements.

(9) If a drug's container is made, formed, or filled as to be misleading.

(10) If a drug is an imitation of another drug.

(11) If a drug is offered for sale under the name of another drug.

(12) If a drug is or purports to be or is represented to be a drug composed wholly or partly of insulin, unless:

(A) the drug is from a batch with respect to which a certificate or release has been issued under Section 506 of the Federal Act; and

(B) the certificate or release is in effect with respect to the drug.

(13) If a drug is or purports to be or is represented to be a drug composed wholly or partly of any kind of penicillin, streptomycin, chloretetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative of those drugs, unless:

(A) the drug is from a batch with respect to which a certificate or release has been issued under Section 507 of the Federal Act; and

(B) the certificate or release is in effect with respect to that drug.

However, this subdivision does not apply to any drug or class of drugs exempted by regulations promulgated under Section 507(c) or 507(d) of the Federal Act.

(14) If a drug or device is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling of the drug or device.

(15) Under the conditions described in section 6 of this chapter.

As added by P.L.2-1993, SEC.25. Amended by P.L.17-2001, SEC.3.

IC 16-42-3-5

Exemption of drugs or devices in transit for further processing,

labeling, or repackaging

Sec. 5. A drug or device that, in accordance with the practice of the trade, is to be processed, labeled, or repacked in substantial quantities at an establishment other than the establishment where the drug or device was originally processed or packed, is exempt from the labeling and packaging requirements of IC 16-42-1 through IC 16-42-4 while the drug or device is in transit in intrastate commerce from one (1) establishment to the other if the transit is made in good faith for completion purposes only. However, the drug or device is otherwise subject to the applicable provisions of IC 16-42-1 through IC 16-42-4.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-6

Drugs dispensed on prescription

Sec. 6. (a) This section applies to a drug intended for use by humans that:

(1) is a habit forming drug to which section 4(4) of this chapter applies;

(2) because of:

(A) the drug's toxicity or other potential for harmful effect;

(B) the method of the drug's use; or

(C) the collateral measures necessary to the drug's use;

is not safe for use except under the supervision of a practitioner licensed by law to administer the drug; or

(3) is limited by an approved application under Section 505 of the Federal Act or section 7 or 8 of this chapter to use under the professional supervision of a practitioner licensed by law to administer the drug.

(b) A drug described in subsection (a) may be dispensed only:

(1) upon a written or an electronically transmitted prescription of a practitioner licensed by law to administer the drug;

(2) upon an oral prescription of the practitioner that is reduced promptly to writing and filed by the pharmacist or pharmacist intern (as defined in IC 25-26-13-2); or

(3) by refilling a prescription if the refilling is authorized by the prescriber either in the original prescription, by an electronically transmitted order that is recorded in an electronic format, or by oral order that is reduced promptly to writing or is entered into an electronic format and filed by the pharmacist or pharmacist intern (as defined in IC 25-26-13-2).

(c) If a prescription for a drug described in subsection (a) does not indicate how many times the prescription may be refilled, if any, the prescription may not be refilled unless the pharmacist is subsequently authorized to do so by the practitioner.

(d) The act of dispensing a drug contrary to subsection (a), (b), or (c) is considered to be an act that results in a drug being misbranded while held for sale.

(e) A drug dispensed by filling or refilling a prescription of a practitioner licensed by law to administer the drug is exempt from

the requirements of section 4(2), 4(3), 4(4), 4(5), 4(6), 4(7), 4(8), and 4(9) of this chapter if the drug bears a label containing the following:

(1) The name and address of the dispenser.

(2) The serial number and date of the prescription or of the prescription's filling.

(3) The name of the drug's prescriber and, if stated in the prescription, the name of the patient.

(4) The directions for use and cautionary statements, if any, contained in the prescription.

This exemption does not apply to any drugs dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or to a drug dispensed in violation of subsection (a), (b), (c), or (d).

(f) The state department may adopt rules to remove drugs subject to section 4(4) of this chapter, section 7 of this chapter, or section 8 of this chapter from the requirements of subsections (a) through (d) when the requirements are not necessary for the protection of public health. Drugs removed from the prescription requirements of the Federal Act by regulations issued under the Federal Act may also, by rules adopted by the state department, be removed from the requirement of subsections (a) through (d).

(g) A drug that is subject to subsections (a) through (d) is considered to be misbranded if at any time before dispensing the drug's label fails to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: State Law Prohibits Dispensing Without Prescription". A drug to which subsections (a) through (d) do not apply is considered to be misbranded if, at any time before dispensing, the drug's label bears the caution statement described in this subsection.

(h) This section does not relieve a person from a requirement prescribed by or under authority of law with respect to drugs included within the classifications of narcotic drugs or marijuana as defined in the applicable federal and state laws relating to narcotic drugs and marijuana.

(i) A drug may be dispensed under subsection (b) upon an electronically transmitted prescription only to the extent permitted by federal law.

As added by P.L.2-1993, SEC.25. Amended by P.L.144-1996, SEC.12; P.L.204-2005, SEC.4.

IC 16-42-3-7

New drugs; federal qualification; testing; application to introduce drug

Sec. 7. (a) This section does not apply under the circumstances described in section 9 of this chapter.

(b) A person may not sell, deliver, offer for sale, hold for sale, give away, or introduce into intrastate commerce any new drug unless:

(1) an application to sell, deliver, offer for sale, hold for sale, give away, or introduce into intrastate commerce a new drug

has been approved and the approval has not been withdrawn under Section 505 of the Federal Act; or

(2) if not subject to the Federal Act the drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling of the drug.

(c) Before selling or offering for sale the new drug, there must be filed with the state department an application setting forth the following:

(1) Full reports of investigations that have been made to show whether or not the drug is safe for use and whether the drug is effective in use.

(2) A full list of the articles used as components of the drug.

(3) A full statement of the composition of the drug.

(4) A full description of the methods used in and the facilities and controls used for the manufacture, processing, and packing of the drug.

(5) Such samples of the drug and of the articles used as components of the drug that the state department requires.

(6) Specimens of the labeling proposed to be used for the drug.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-8

New drugs; time for application to take effect

Sec. 8. (a) This section does not apply under the circumstances described in section 9 of this chapter.

(b) An application provided for under section 7 of this chapter becomes effective on the one hundred eightieth day after the filing of the application. However, if the state department finds, after due notice to the applicant and giving the applicant an opportunity for a hearing that:

(1) the drug is not safe or not effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling of the drug;

(2) the methods used in and the facilities and controls used for the manufacture, processing, and packing of the drugs are inadequate to preserve the drug's identity, strength, quality, and purity; or

(3) based on a fair evaluation of all material facts, that the labeling is false or misleading in any particular;

the state department shall, before the effective date of the application, issue an order refusing to permit the application to become effective.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-9

New drugs; exemption

Sec. 9. (a) Sections 7 and 8 of this chapter do not apply to the following:

(1) To a drug dispensed on a written or an electronically

transmitted prescription signed by or with an electronic signature of a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail) if the physician, dentist, or veterinarian is licensed by law to administer the drug, and the drug bears a label containing the name and place of business of the dispenser, the serial number and date of the prescription, and the name of the physician, dentist, or veterinarian.

(2) To a drug exempted by rule of the state department and that is intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs.

(3) To a drug sold in Indiana or introduced into intrastate commerce at any time before the enactment of the Federal Act, if the drug's labeling contained the same representations concerning the conditions of the drug's use.

(4) To any drug that is licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.) or under the Animal Virus-Serum Toxin Act of March 4, 1913 (13 Stat. 832; 21 U.S.C. 151 et seq.).

(5) To a drug subject to section 4(10) of this chapter.

(b) Rules exempting drugs intended for investigational use under subsection (a)(2) may, within the discretion of the state department among other conditions relating to the protection of the public health, provide for conditioning the exemption upon the following:

(1) The submission to the state department, before any clinical testing of a new drug is undertaken, of reports by the manufacturer or the sponsor of the investigation of the drug or preclinical tests, including tests on animals, of the drug adequate to justify the proposed clinical testing.

(2) The manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of the investigators that patients to whom the drug is administered will be under the manufacturer's or sponsor's personal supervision or under the supervision of investigators responsible to the manufacturer or sponsor and that the manufacturer or sponsor will not supply the drug to any other investigator or to clinics for administration to human beings.

(3) The establishment and maintenance of the records and the making of the reports to the state department by the manufacturer or the sponsor of the investigation of the drug of data (including analytical reports by investigators) obtained as the result of the investigational use of the drug that the state department finds will enable the state department to evaluate the safety and effectiveness of the drug if an application is filed under section 8 of this chapter.

(c) Rules exempting drugs intended for investigational use under subsection (a)(2) must provide that the exemption is conditioned

upon the manufacturer or the sponsor of the investigation requiring that experts using the drugs for investigational purposes certify to the manufacturer or sponsor that the experts will inform any human beings to whom the drugs or any controls used in connection with the drugs are being administered that the drugs are being used for investigational purposes and will obtain the consent of the human beings or their representatives, except where they consider it not feasible or, in their professional judgment, contrary to the best interests of the human beings.

(d) This section does not require a clinical investigator to submit directly to the state department reports on the investigational use of drugs. The regulations adopted under Section 505(i) of the Federal Act are the rules in Indiana. The state may adopt rules, whether or not in accordance with regulations promulgated under the Federal Act.

As added by P.L.2-1993, SEC.25. Amended by P.L.204-2005, SEC.5.

IC 16-42-3-10

New drugs; revocation of order refusing application to take effect; revocation of approved application

Sec. 10. (a) An order refusing to permit an application under section 7 or 8 of this chapter to become effective may be revoked by the state department.

(b) The state department may, after affording an opportunity for public hearing and judicial appeal, revoke an application approved under section 7 or 8 of this chapter if the state department finds any of the following:

(1) That the drug, based on evidence acquired after approval, may not be safe or effective for the intended use.

(2) That the facilities or controls used in the manufacture, processing, or labeling of the drug may present a hazard to the public health.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-11

Representation of antiseptic

Sec. 11. The representation of a drug in the labeling or advertisement as an antiseptic is considered to be a representation that the drug is a germicide, except if a drug purporting to be or represented as an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or other use involves prolonged contact with the body.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-12

Violation of chapter; offenses

Sec. 12. (a) Except as otherwise provided, a person who recklessly violates or fails to comply with this chapter commits a Class B misdemeanor.

(b) Each day a violation continues constitutes a separate offense.

As added by P.L.2-1993, SEC.25.